

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Michael Buschle *et al.*

Serial No.: 10/550,820

Filed: September 23, 2005

For: USE OF ALUM AND A TH1 IMMUNE  
RESPONSE INDUCING ADJUVANT  
FOR ENHANCING IMMUNE RESPONSE

Group Art Unit: 1645

Examiner: Unknown

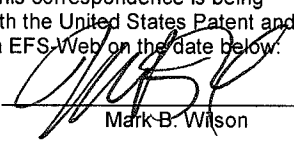
Atty. Dkt. No.: SONN:077US

Confirmation No.: 8341

**CERTIFICATE OF ELECTRONIC TRANSMISSION**

I hereby certify that this correspondence is being  
electronically filed with the United States Patent and  
Trademark Office via EFS-Web on the date below:

April 17, 2007  
Date

  
Mark B. Wilson

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to

be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/SONN:077US.

This application may be related by inventorship and subject matter to co-pending U.S. application numbers:

10/505,929, filed March 10, 2005;

10/512,885, filed October 28, 2004;

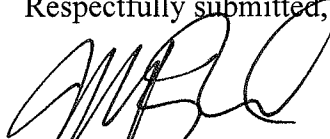
10/512,790, filed October 27, 2004;

10/550,754, filed September 23, 2005;

10/564,429, filed April 24, 2006.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Mark B. Wilson

Reg. No. 37,259

Attorney for Applicants

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Date: April 17, 2007

Form PTO-1449 (modified)		Atty. Docket No. SONN:077US	Serial No. 10/550,820
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Michael Buschle <i>et al.</i>	
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U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1-3</i>	Other Art <i>See Page 3-10</i>	

### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	2003/0162738	08/28/03	Egyed <i>et al.</i>	514	44	12/06/02
	A2	5,663,153	09/02/97	Hutcherson <i>et al.</i>	514	44	06/06/95
	A3	5,683,864	11/04/97	Houghton <i>et al.</i>	435	5	07/07/92
	A4	5,723,335	03/03/98	Hutcherson <i>et al.</i>	435	375	09/11/96
	A5	6,037,135	03/14/00	Kubo <i>et al.</i>	435	7.24	11/29/93
	A6	6,150,087	11/21/00	Chien	435	5	05/18/95
	A7	6,413,517	07/02/02	Sette <i>et al.</i>	424	185.1	01/21/98

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	B1	A 1973/2000	11/23/00	Austria	English
	B2	A 805/2001	05/21/00	Austria	English
	B3	EP 0 468 520	01/29/92	Europe	English
	B4	WO 00/11186	03/02/00	WIPO	English
	B5	WO 00/23105	04/27/00	WIPO	English
	B6	WO 00/31542	06/02/00	WIPO	English
	B7	WO 00/44775	08/03/00	WIPO	English
	B8	WO 01/17551	03/15/01	WIPO	English
	B9	WO 01/21189	03/29/01	WIPO	English
	B10	WO 01/24822	04/12/01	WIPO	English
	B11	WO 01/54719	08/02/01	WIPO	English
	B12	WO 01/72782	10/04/01	WIPO	English
	B13	WO 01/78767	10/25/01	WIPO	English

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	B14	WO 01/93903	12/13/01	WIPO	English
	B15	WO 01/93905	12/13/01	WIPO	English
	B16	WO 02/053185	07/11/02	WIPO	English
	B17	WO 02/095027	11/28/02	WIPO	English
	B18	WO 02/13857	02/21/02	WIPO	English
	B19	WO 02/32451	04/25/02	WIPO	English
	B20	WO 02/33127	04/25/02	WIPO	English
	B21	WO 03/047602	06/12/03	WIPO	English
	B22	WO 03/073097	09/04/03	WIPO	English
	B23	WO 2004/014936	02/19/04	WIPO	French (English Abstract)
	B24	WO 2004/024182	03/25/04	WIPO	English
	B25	WO 92/03458	03/05/92	WIPO	English
	B26	WO 93/00365	01/07/93	WIPO	English
	B27	WO 94/20127	09/15/94	WIPO	English
	B28	WO 94/25601	11/10/94	WIPO	English
	B29	WO 95/12766	05/11/95	WIPO	English
	B30	WO 95/22317	08/24/95	WIPO	English
	B31	WO 95/25122	09/21/95	WIPO	English
	B32	WO 95/27733	10/19/95	WIPO	English
	B33	WO 95/27901	10/19/95	WIPO	English
	B34	WO 96/02555	02/01/96	WIPO	English
	B35	WO 97/30721	08/28/97	WIPO	German (English Abstract)
	B36	WO 98/15287	04/16/98	WIPO	English

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	B38	WO 98/18810	05/07/98	WIPO	English
	B39	WO 98/37919	09/03/98	WIPO	English
	B40	WO 98/40100	09/17/98	WIPO	English
	B41	WO 98/52581	11/26/98	WIPO	English
	B42	WO 98/52962	11/26/98	WIPO	English
	B43	WO 99/15259	04/01/99	WIPO	English
	B44	WO 99/33488	06/08/99	WIPO	English
	B45	WO 99/38528	08/05/99	WIPO	German (English Abstract)
	B46	WO 99/51259	10/14/99	WIPO	English
	B47	WO 99/56755	11/11/99	WIPO	English
	B48	WO 99/63941	12/16/99	WIPO	English

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	C1	"Aluminiumhydroxide," Röempp, 10 <sup>th</sup> Ed., pp. 139-140, 2006 (in German).
	C2	Anthony <i>et al.</i> , "Comprehensive determinant mapping of the hepatitis C-specific CD8 cell repertoire reveals unpredicted immune hierarchy," <i>Clinical Immunology</i> , 103(3):264-276, 2002.
	C3	Battegay <i>et al.</i> , "Patients with chronic hepatitis C have circulating cytotoxic T cells which recognize hepatitis C virus-encoded peptides binding to HLA-A2.1 molecules," <i>J. Virol.</i> , 69(4):2462-2470, 1995.
	C4	Bellentani <i>et al.</i> , "Epidemiology of hepatitis C virus infection in Italy: the slowly unraveling mystery," <i>Microbes Infect.</i> , 2(14):1757-63, 2000.
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Exam. Init.	Ref. Des.	Citation
	C6	Blake <i>et al.</i> , "Use of combinatorial peptide libraries to construct functional mimics of tumor epitopes recognized by MHC class I-restricted cytolytic T lymphocytes," <i>J. Exp. Med.</i> , 184:121-130, 1996.
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	C8	Bullock <i>et al.</i> "Initiation codon scanthrough verses termination codon readthrough demonstrates strong potential for MHC class I restricted cryptic epitope expression," <i>Journal of Experimental Medicine</i> , 186:1051-1058, 1997.
	C9	Chang <i>et al.</i> , "Identification of HLA-A3 and -B7-restricted CTL response to hepatitis C virus in patients with acute and chronic hepatitis C," <i>J. Immunol.</i> , 162:1156-1164, 1999.
	C10	Chen <i>et al.</i> , "A novel influenza A virus mitochondrial protein that induces cell death," <i>Nature Medicine</i> , 7:1306-1312, 2001.
	C11	Chen <i>et al.</i> , "Efficient class II major histocompatibility complex presentation of endogenously synthesized hepatitis C virus core protein by Epstein-Bar virus-transformed B-lymphoblastoid cell lines to CD4 <sup>+</sup> T cells," <i>Journal of Virology</i> , 72(10):8301-8308, 1998.
	C12	Cho <i>et al.</i> , "Activation of human neutrophils by a synthetic anti-microbial peptide, KLKLLLLLK-NH <sub>2</sub> , via cell surface calreticulin," <i>Eur. J. Biochem.</i> , 266:878-885, 1999.
	C13	Cox <i>et al.</i> , "Identification of a peptide recognized by five melanoma-specific human cytotoxic t cell lines," <i>Science</i> , 264:716-719, 1994.
	C14	Di Bisceglie <i>et al.</i> , "New therapeutic strategies for hepatitis C," <i>Hepatology</i> , 35:224-231, 2002.
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	C17	Duenas-Carrera <i>et al.</i> , "Enhancement of the immune response generated against hepatitis C virus envelope proteins after DNA vaccination with polyprotein-encoding plasmids," <i>Biotechnol. Appl. Biochem.</i> , 35:205-212, 2002.
	C18	Elliot <i>et al.</i> "Recognition of out-of-frame major histocompatibility complex class I-restricted epitopes in vivo," <i>European Journal of Immunology</i> , 26:1175-1179, 1996.

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	C19	Farci and Purcell, "Clinical significance of hepatitis C virus genotypes and quasispecies," <i>Semin Liver Dis.</i> , 20(1):103-26, 2000.
	C20	Fleckenstein <i>et al.</i> , "New ligands binding to the human leukocyte antigen class II molecule DRB+0101 based on the activity pattern of an undecapeptide library," <i>European Journal of Biochemistry</i> , 240:71-77, 1996.
	C21	Greten and Schneck, "Development and use of multimeric major histocompatibility complex molecules," <i>Clinical and Diagnostic Laboratory Immunology</i> , 9(2):216-220, 2002.
	C22	Gruener <i>et al.</i> , "Sustained dysfunction of antiviral CD8+ T lymphocytes after infection with hepatitis C virus," <i>J. Virol.</i> , 75:5550-5558, 2001.
	C23	Hammer <i>et al.</i> , "Promiscuous and allele-specific anchors in HLA-DR-binding peptides," <i>Cell</i> , 74:197-203, 1993.
	C24	Heemels and Ploegh, "Generation, translocation and presentation of mhc class I-restricted peptides," <i>Annu Rev Biochem</i> , 64:463-491, 1995.
	C25	Heile <i>et al.</i> , "Evaluation of hepatitis C virus glycoprotein E2 for vaccine design: an endoplasmic reticulum-retained recombinant protein is superior to secreted recombinant protein and DNA-based vaccine candidates," <i>J. Virol.</i> , 74(15):6885-6892, 2000.
	C26	Hemmer <i>et al.</i> , "Predictable TCR antigen recognition based on peptide scans leads to the identification of agonist ligands with no sequence homology," <i>J. Immunol.</i> , 160:3631-3636, 1998.
	C27	Hemmer <i>et al.</i> , "The use of soluble synthetic peptide combinatorial libraries to determine antigen recognition of T cells," <i>J. Peptide Res.</i> , 52:338-345, 1998.
	C28	HLA-prevalence studies, In: HLA 1998, (Gjertson and Terasaki, eds.) American Society for Histocompatibility and Immunogenetics, Lenexa, Kansas, pp. 103-263, 1998.
	C29	Hoffmann <i>et al.</i> , "Mapping of Immunodominant CD4+ T Lymphocyte Epitopes of Hepatitis C Virus Antigens and Their Relevance During the Course of Chronic Infection," <i>Hepatology</i> , 21(3):632-638, 1995.
	C30	Hunziker <i>et al.</i> , "In vitro studies of core peptide-bearing immunopotentiating reconstituted influenza viroosomes as a non-live prototype vaccine against hepatitis C virus," <i>International Immunology</i> , 14(6):615-626, 2002.

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Exam. Init.	Ref. Des.	Citation
	C31	Ibe <i>et al.</i> , "Identification and characterization of a cytotoxic T cell epitope of hepatitis C virus presented by HLA-B*3501 in acute hepatitis," <i>J. Gen. Virol.</i> , 79:1735-1744, 1998.
	C32	Inchauspe and Feinstone, "Development of a hepatitis C virus vaccine," <i>Clinics in Liver Disease</i> , 7:243-259, 2003.
	C33	Keilholz <i>et al.</i> , "Immunologic monitoring of cancer vaccine therapy: results of a workshop sponsored by the Society for Biological Therapy," <i>J Immunother.</i> , 25(2):97-138, 2002.
	C34	Kern <i>et al.</i> , "Analysis of cd8 t cell reactivity to cytomegalovirus using protein-spanning pools of overlapping pentadecapeptides," <i>Eur J Immun</i> , 30:1676-1682, 2000.
	C35	Kern <i>et al.</i> , "Target structures of the cd8+-t-cell response to human cytomegalovirus: the 72-kilodalton major immediate-early protein revisited," <i>J Virol</i> , 73:8179-8184, 1999.
	C36	Klein, <i>Natural History of the MHC</i> , John Wiley and Sons, 1986.
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	C38	Koziel <i>et al.</i> , "Hepatitis C virus (HCV)-specific cytotoxic T lymphocytes recognize epitopes in the core and envelope proteins of HCV," <i>J. Virol.</i> , 67:7522-7532, 1993.
	C39	Koziel <i>et al.</i> , "HLA class I-restricted cytotoxic T lymphocytes specific for hepatitis C virus. Identification of multiple epitopes and characterization of patterns of cytokine release," <i>J. Clin. Invest.</i> , 96:2311-2321, 1995.
	C40	Kurokohchi <i>et al.</i> , "A novel cytotoxic T-cell epitope presented by HLA-A24 molecule in hepatitis C virus infection," <i>J. Hepatology</i> , 34:930-935, 2001.
	C41	Kwok <i>et al.</i> , "Rapid epitope identification from complex class-II-restricted T-cell antigens," <i>Trends in Immunology</i> , 22(11):583-588, 2001.
	C42	Lamonaca <i>et al.</i> , "Conserved Hepatitis C Virus Sequences Are Highly Immunogenic for CD4+ T Cells: Implications for Vaccine Development," <i>Hepatology</i> , 30(4):1088-1098, 1999.
	C43	Lauer <i>et al.</i> , "Comprehensive analysis of CD8+-T-cell responses against hepatitis C virus reveals multiple unpredicted specificities," <i>Journal of Virology</i> , 76(12):6104-6113, 2002.
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	C45	Leroux-Roels <i>et al.</i> , "Lymphoproliferative Responses to Hepatitis C Virus Coes, E1, E2, and NS3 in Patients With Chronic Hepatitis C Infection Treated With Interferon Alfa," <i>Hepatology</i> , 23(1):8-16, 1996.
	C46	Liang <i>et al.</i> , "Pathogeneis, Natural History, Treatment, and Prevention of Hepatitis C," <i>Ann Intern Med.</i> , 132(4):296-305, 2000.
	C47	Maecker <i>et al.</i> , "Use of overlapping peptide mixtures as antigens for cytokine flow cytometry," <i>J Immunol Methods</i> , 255:27-40, 2001.
	C48	Malarkannan <i>et al.</i> , "Presentation of out-of-frame peptide/MHC class I complexes by a novel translation initiation mechanism," <i>Immunity</i> , 10:681-690, 1999.
	C49	Maynard <i>et al.</i> "An alternative translation reading frame encodes an immunodominant retroviral CTL determinant expressed by an immunodeficiency-causing retrovirus," <i>J. of Immunology</i> , 160:39-50, 1998.
	C50	Maynard <i>et al.</i> "Non-traditionally derived CTL epitopes: exceptions that prove the rules?" <i>Immunology Today</i> , 19:551-556, 1998.
	C51	McCluskie <i>et al.</i> , "Parenteral and mucosal prime-boost immunization strategies in mice with hepatitis B surface antigen and CpG DNA," <i>Fems Immunol and Medical Microbiol</i> , 32:179-185, 2002.
	C52	Morgan <i>et al.</i> , "The influence of exogenous peptide on beta2-microglobulin exchange in the HLA complex: analysis in real time," <i>Immunogenetics</i> , 48:98-107, 1998.
	C53	Nakajima <i>et al.</i> , "Chemotherapeutic activity of synthetic antimicrobial peptides: correlation between chemotherapeutic activity and neutrophil-activating activity," <i>FEBS Lett.</i> , 415:64-66, 1997.
	C54	Novak <i>et al.</i> , "Tetramer-guided epitope mapping: rapid identification and characterization of immunodominant CD4 <sup>+</sup> T cell eiptopes from complex antigens," <i>The Journal of Immunology</i> , 166:6665-6670, 2001.
	C55	Parker <i>et al.</i> , "Scheme for ranking potential HLA-A2 binding peptides based on independent binding of individual peptide side-chains," <i>J. Immunol.</i> , 152:163, 1994.
	C56	Plotkin, "Vaccination against cytomegalovirus, the changeling demon," <i>Pediatr Infect Dis J</i> , 18:313-325, 1999.

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	C57	Rammensee <i>et al.</i> , "SYFPEITHI: database for MHC ligands and peptide motifs," <i>Immunogenetics</i> , 50:213-219, 1999.
	C58	Reddehase, "The immunogenicity of human and murine cytomegaloviruses," <i>Curr Opin Immunol</i> , 12:390-396, 2000.
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Form PTO-1449 (modified)	Atty. Docket No. SONN:077US	Serial No. 10/550,820
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)	Applicant Michael Buschle <i>et al.</i>	
	Filing Date: September 23, 2005	Group: 1645
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1-3</i>	Other Art <i>See Page 3-10</i>

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
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Exam. Init.	Ref. Des.	Citation
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